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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,244	12/06/2001	Robert Sixto JR.	SYN-064 A	5798
44338	7590	10/25/2005	EXAMINER	
FELDMANGALE, P.A. MIAMI CENTER, 19TH FLOOR 201 SOUTH BISCAYNE BOULEVARD MIAMI, FL 33131				EREZO, DARWIN P
ART UNIT		PAPER NUMBER		
		3731		

DATE MAILED: 10/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/010,244	SIXTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 August 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 13-25 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 26-35 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/05 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 28, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The recited claims recite the limitation of releasably coupling the two arms to the bridge. However, the applicant has not provided any disclosure in the specification or drawings to support this limitation, i.e., as best understood by the examiner, the arms and bridge are integral/one-piece and not separable. Therefore, the claims are not enabled.

***Claim Rejections - 35 USC § 102***

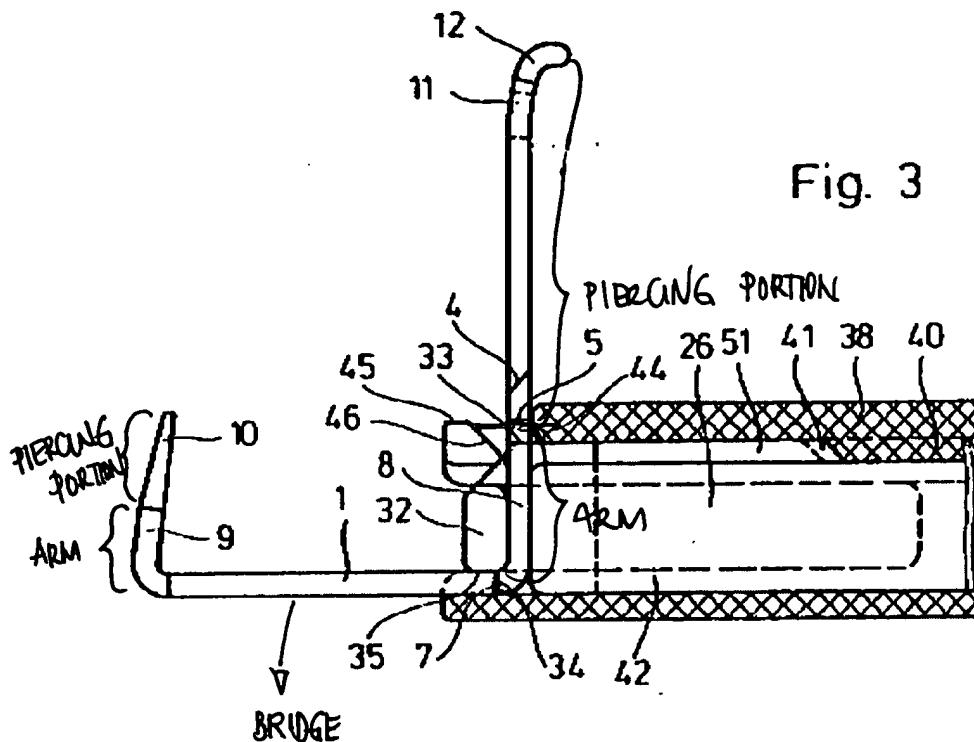
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,522,823 to Kuntz et al.

6. As to claim 1, Fig. 3 of Kuntz, which is shown below, teaches a medical method comprising advancing a clip over body tissue, said clip having two substantially parallel arms each having a respective piercing portion and a bridge coupling the two arms, such that the body tissue is located between the two arms and such that the clip applies force to the body tissue (col. 6, lines 17-19); and subsequently bending the piercing portion of at least one of the two arms through more than one half a thickness of the body tissue, said two arms remaining substantially parallel throughout the time the piercing portion of the at least one arm is bent (transition from Fig. 3 to Fig. 4).



11. Claims 5-12, 27 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,086,600 to Kortenbach in view of Kuntz et al.

Kortenbach teaches a medical method of using a clip applier for fastening folded tissues together; wherein the tissue is the fundus of the stomach (col. 1, line 17) that is folded upon itself longitudinally (Fig. 14); wherein a grasping instrument 42 is used to grab the fundus; wherein a fastener (46,57) is used to pierce through the folded tissues; wherein the device is a single instrument; and wherein the tissue are separate folds of tissue. Kortenbach teaches a clip that comprises two separable portions and fails to teach a clip having two substantially parallel arms and a bridge coupling the arms.

However, Kuntz teaches a clip and a clip applier that is fully capable of piercing through folded tissues. Furthermore, as recited in the 102 rejection above, Kuntz teaches the structural limitations of the recited clip.

Therefore, since Kuntz and Kortenbach both teach clip applicators that pierce through tissues, it would have been obvious to one of ordinary skill in the art to use either the clip applier of Kuntz or the clip applier of Kortenbach since both applicators perform the same function of providing a tissue fastener and that the clip applier of Kuntz would perform equally as well in the method taught by Kortenbach. Furthermore, the clip provided by Kuntz allows for easier removal of the clip by unhooking the piercing portions from each other.

#### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1-12 and 26-35 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Darwin P. Erez  
Examiner  
Art Unit 3731

de